

## **REMARKS**

### **I. INTRODUCTION**

Paragraph [0019] of the Specification has been amended to correct a typographical error. Claims 1, 2, 4, 6-8, 10-19, 23-25, and 27 have been amended to correct typographical errors and to more distinctly claim the subject matter of the invention. No new matter has been added. Thus, claims 1-19 and 23-27 remain pending in this application. In view of the above amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

### **II. THE CLAIM OBJECTION SHOULD BE WITHDRAWN**

The Examiner objected to claim 18 because it was "dependent on itself." Claim 18 has been amended to depend on claim 15. Claims 16-25 have been similarly amended. Therefore, it is respectfully submitted that the claim objection should be withdrawn.

### **III. THE REJECTION UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN**

The Examiner rejected claim 11 under 35 U.S.C. § 112 as indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Examiner stated that there was insufficient antecedent basis for the recited limitation "the catheter is a dialysis catheter."

In view of the above amendment to claim 11, it is respectfully submitted that this claim fully complies with § 112 and that this rejection should be withdrawn.

### **IV. THE REJECTIONS UNDER 35 U.S.C. § 102(b) SHOULD BE WITHDRAWN**

Claims 1-4, 12, 14, and 23 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,524,805 to Hoffman.

Amended claim 1 recites "[a] valve apparatus for medical applications, comprising a *first flexible disk* extending across a first lumen through which a flow of materials is to be controlled, the first flexible disk including a plurality of first movable elements formed on opposite sides of at least one first slit extending through the first flexible disk, the first moveable members being biased so that, when a pressure less than a predetermined threshold value is applied to the first flexible disk, the first moveable elements are maintained in a closed position in which no flow is permitted past the first flexible disk and, when a pressure at least as great as the threshold value

is applied to the first flexible disk, the first moveable elements are moved to an open position separated from one another along the at least one first slit permitting flow through the first lumen.”

In contrast, Hoffman describes a duckbill valve 10 controlling a direction of fluid flow through a lumen. The valve 10 comprises a generally cylindrical body member 12 defining an axial fluid passageway 14 extending from an inlet end 16 to an outlet end 18 provided with an outlet slit. *Hoffman*, col. 3, ll. 6-9. The body member 12 progressively narrows from the inlet end 16 to the outlet end 18 to define a pair of opposed sealing lips 20 and 22 which meet at an outlet slit 19. *Id.* at col. 3, ll. 9-13. The lips 20 and 22 are normally urged to a closed position. *Id.* at col. 3, ll. 13-14.

Claim 1 recites a *flexible disk* which is substantially structurally different from the duckbill valve 10 of Hoffman. Furthermore, it is respectfully submitted that this duckbill shape of the valve 10 of Hoffman is critical to its function -- i.e., this shape enables the valve 10 to limit flow therethrough to a single direction.. *Id.* at col. 4, ll. 35-38. Fluid flow enters axial passageway 14 through inlet end 16, flows through the body member 12 to outlet end 18, where fluid pressure forces the flexible elastomeric material of the lips 20, 22 away from one another to open the outlet slit 19. *Id.* at col. 4, ll. 37-44. Due to the duckbill shape of the valve 10, when the direction of fluid flow is stopped or reversed, “the compressive force exerted by lips 24, 26...effectively closes the outlet end 18 of valve 10 by forcing lips 20, 22 towards sealing engagement against each other.” *Id.* at col. 4, ll. 46-51. That is, fluid pressure in the opposite direction operates on the duckbill shape forcing the lips 20, 22 toward each other to add to the biasing force urging the lips 20, 22 to seal the slit 19. A *flexible disk* would frustrate this purpose of a duckbill valve.

Thus, it is respectfully submitted that Hoffman neither shows nor suggests a valve comprising “a *first flexible disk* extending across a first lumen through which a flow of materials is to be controlled,” as recited in amended claim 1, and that claim 1 is allowable for this reason. Furthermore, it is respectfully submitted that any proposed modification or combination which eliminates this duckbill shape from the apparatus of Hoffman without supplying some other means for ensuring unidirectional flow is taught away from by this reference.

Because claims 2-4, 12, and 14 depend from and therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Amended claim 15 recites a dialysis connector comprising “a valve housing” with a “flow passage” and “a valve element mounted within the flow passage of the housing, the valve element including a *flexible disk* extending across the flow passage, the flexible disk including a plurality of movable elements formed on opposite sides of a first slit extending through the flexible disk, the moveable members being biased so that, when a pressure less than a predetermined threshold value is applied to the flexible disk, the moveable elements are maintained in a closed position in which no flow is permitted past the flexible disk and, when a pressure at least as great as the threshold value is applied to the flexible disk, the moveable elements are moved to an open position separated from one another along the first slit permitting flow through the flow passage.”

For the same reasons as described above in regard to claim 1, it is respectfully submitted that Hoffman neither shows nor suggests “a *flexible disk* extending across the flow passage,” as recited in claim 15. Because claim 23 depends from and therefore includes all of the limitations of claim 15, it is respectfully submitted that this claim is also allowable.

**V. THE REJECTIONS UNDER 35 U.S.C. § 103(a) SHOULD BE WITHDRAWN**

Claims 5-7, 9-11, 13, 15-17, and 24-27 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Hoffman in view of Patent No. 5,810,789 to Powers et al. (“Powers”). The Examiner stated that Hoffman disclosed a valve apparatus that includes all of the limitations as recited in claim 1, but does not describe the addition of a housing attached to a dual lumen catheter with a valve apparatus in each lumen to regulate fluid flow. *11/30/05 Office Action*, p. 4. To cure this deficiency the Examiner cites Powers. However, it is respectfully submitted that Powers does not cure the deficiencies presented by the anticipation rejections of the independent claims. Powers does not show or suggest a “*flexible disk*” as recited in claims 1, 15, and 26 from which these claims depend. Moreover, as stated above, any modification that would replace the duckbill of Hoffman without providing for the maintenance of one way only flow, is taught away from by that reference.

In addition, it is respectfully submitted that Powers does not show or suggest a valve with a slit having “first moveable members being biased so that, when a pressure less than a predetermined threshold value is applied to the first flexible disk, the first moveable elements are maintained in a closed position in which no flow is permitted past the first flexible disk,” as recited in claims 1 and 15.

Because claims 5-7, 9-11, 15-17, and 24-27 depend from and therefore include all of the limitations of claims 1 and 15, it is respectfully submitted that these claims are not rendered obvious by Hoffman in view of Powers, and that this rejection be withdrawn.

Claim 8 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Hoffman in view of Patent No. 6,099,505 to Ryan et al. ("Ryan"). The Examiner stated that Hoffman discloses a device that includes all of the limitations as recited in claim 3, but does not disclose to include another pair of slits intersecting at the end of the first slit. *11/30/05 Office Action*, p. 5. The Examiner cites Ryan to cure this deficiency. However, it is respectfully submitted that Ryan does not cure the deficiencies pointed out in regard to the anticipation rejection of independent claim 1, from which claim 3 depends. Ryan does not show or suggest a "flexible disk," as recited in amended claim 1.

Furthermore, amended claim 8 recites a "valve apparatus according to claim 3, wherein the first flexible disk further includes *a pair of second slits, each of the second slits intersecting a corresponding end of the first slit.*" (Fig. 6) In contrast, Ryan discloses a surgical trocar assembly including a disposable valve assembly with a tricuspid valve. A tricuspid valve is typically constructed with three slits converging at the center of the disk. *Ryan*, col. 7, ll. 50-53. A tricuspid valve has only one set of second slits at one end of the first slit. (Fig. 2f) Therefore, it is respectfully submitted that the valve apparatus of Ryan does not comprise "*a pair of second slits, each of the second slits intersecting a corresponding end of the first slit,*" as recited in claim 8.

It is therefore respectfully submitted that claim 8 is not rendered obvious by Hoffman in view of Ryan, and that this rejection should be withdrawn.

Claims 18 and 19 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Hoffman and Powers as applied to claim 15 above, and in further view of Ryan. The Examiner states that Hoffman and Powers describe a device that discloses all of the limitations as recited in claim 15, but do not disclose to include another pair of slits intersecting at the end of the first slit. *Id.* To cure this deficiency the Examiner cites Ryan. However, it is respectfully submitted that Ryan does not cure the deficiencies left by Hoffman and Powers, as described above, in regard to independent claim 15.

Because claims 18 and 19 depend from, and therefore include, all of the limitations of claim 15, it is therefore respectfully submitted that these claims are not rendered obvious by

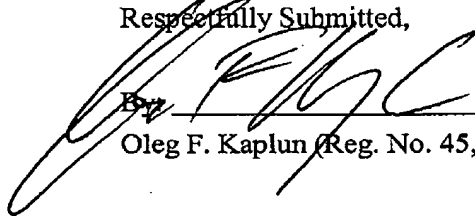
Hoffman and Powers in further view of Ryan, and that this rejection should be withdrawn.

**CONCLUSION**

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, and an early and favorable action on the merits is earnestly solicited.

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Respectfully Submitted,



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